

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

The amendment in claim 38 adding the term “linear correlation” between CD16-specific ADCC activity and the amount of IL-2 is supported by Figure 10, the description of Figure 10 at page 13, lines 16-18 and page 16, lines 18-28 of the originally filed specification. The negative control being an antibody of the same specificity produced by CHO cells is supported by the specification at page 8, lines 5-8. The negative control being the absence of an antibody is supported by the specification at page 10, line 32.

The statement from Nicolas Bihoreau that error in inventorship occurred without deceptive intention was filed on November 12, 2007.

Rejections Under 35 USC 112, Second Paragraph

Claim 38 has been amended to overcome the rejection for indefiniteness. Amended claim 38 recites the features that allow for the selection of a monoclonal antibody having better ADCC activity than a negative control. As disclosed in the specification, because there is a linear correlation between the production of IL-2 by Jurkat CD16 and the ADCC activity of the monoclonal antibodies, the measurement of the rate of production of IL-2 directly relates to the level of ADCC activity of the antibodies. Accordingly, claim 38 recites that “the measurement of the amount of IL-2 is linearly correlated to the CD16-specific ADCC activity.”

The word “effectiveness” has been deleted from claim 38, thereby overcoming this rejection.

The recitation IL-2 in amended claim 38 has proper antecedent basis.

As applicants have noted above, the correlation between CD16-specific ADCC activity and the amount of IL-2 is linear. In addition to Figure 10, this is supported by the specification at page 16, lines 18-28.

Rejections Under 35 USC 112, First Paragraph, Enablement

Applicants contend that the present invention could be practiced without an undue burden. The correlation between ADCC activity and IL-2 production is linear, which one of skill in art would be able to readily ascertain from the specification. Therefore, based on this relationship, one of skill in the art could practice the claimed method.

The Examiner has stated that Siberil et al. discloses that anti-Rh(D) antibodies prevent alloimmunization by engaging both the activating Fc γ R and the inhibitory Fc γ RIIB1, and that inhibiting IL-2 production correlates with a strong ADCC effect. This is not in contradiction with the present invention. The effector cells used in Siberil et al to test the production of IL-2 induced by the binding of the Fc region of the antibody and Fc γ RIIB1 receptor, are tumor cell line II A.1.6 transfected with human Fc γ RII. These cells express Fc γ RIIB, and do not express Fc γ RIII. On the contrary, Jurkat CD16 does not express Fc γ RIIB but only express Fc γ RIII. The binding of the antibodies to Fc γ RIIB and Fc γ RIII is disclosed by Siberil et al., to be on different effector cells, each of these effector cells expressing only one kind of Fc γ receptor. Therefore, even if some antibodies can inhibit secretion of IL-2 mediated by Fc γ RIIB, this is unconnected with the invention.

Rejections Under 35 USC 112, First Paragraph, Written Description

Although applicants do not agree with the outstanding rejection for lack of written description, the phrase “the antibody being activated by the antigen, and the antigen being different from the CD16”, has been deleted from amended claim 38.

Rejections Under 35 USC 102, Anticipation

Claim 38 is rejected as being anticipated by Pullyblank et al. Pullyblank et al., however, cannot anticipate the present invention because there is no disclosure of a linear correlation between the ADCC activity and the production of IL-2 by Jurkat CD16. This linear correlation permits the selection of antibodies in accordance with the present invention. Without knowledge of this linear correlation, no relation can be made between ADCC activity and IL-2 production of Jurkat CD16, and consequently no selection of an antibody

that has a good reactivity of its Fc region toward Fc γ RIII can be realized. Accordingly, since Pullyblank et al do not disclose all of the features of the present claims, this reference cannot anticipate the present invention.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

By 

Date November 28, 2007
FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

Matthew E. Mulkeen
Attorney for Applicants
Registration No. 44,250